

August 25, 2006

Plan B Shift Threatens to Deepen Rift

Over-Counter Sale Allowed, But Fresh Battles Loom Over Restrictions on Minors

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 August 25, 2006; Page A3

The Food and Drug Administration's decision to allow the emergency contraceptive Plan B to be sold to adults without a prescription will boost the use of the drug, but the move may also widen political and societal fault lines around issues of medicine and reproductive rights.

Plan B, made by **Barr Pharmaceuticals Inc.**, has been at the center of a bitter debate both inside and outside the FDA, which for years stalled the manufacturer's application for over-the-counter status. Yesterday, the agency said that people 18 years or older could get the drug without a prescription, if they show identification proving their age. For women younger than 18, Plan B, also known as the "morning-after" pill, will still require a prescription.

Yesterday, Democratic Sens. Hillary Rodham Clinton of New York and Patty Murray of Washington said they would remove their hold on the nomination of acting FDA Commissioner Andrew von Eschenbach to be formal head of the agency. They had blocked a Senate vote until the FDA made a decision about Plan B.

MORE ON THE DECISION

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- [A Subtle Method for Selling 'Plan B'](#)²
- [Video: Barr CEO comments on decision](#)³
- [WSJ senior special writer John Harwood](#)⁴ on the political fallout.
- [Q&A on Plan B](#)⁵ | [FDA statement](#)⁶ | [Timeline](#)⁷



Antiabortion groups criticized yesterday's decision and said it wouldn't prevent young teens from getting Plan B without a prescription. On the other side, reproductive-rights groups, which had argued that easy access to Plan B would be a vital tool against unintended pregnancies, applauded the decision but said the age restriction was unnecessary.

Plan B effectively functions like a high dose of birth-control pills. When taken within 72 hours following unprotected sex, the product reduces the risk of

pregnancy by as much as 89%. Scientists believe the resulting surge of hormones interferes with ovulation and fertilization or may potentially prevent implantation of a fertilized egg in the uterus. The medical community generally doesn't consider this to be abortion, and the FDA doesn't classify Plan B as an abortion-causing drug, though some antiabortion groups do. Plan B isn't the same as mifepristone, sometimes called RU-486, a prescription-only pill that induces an abortion.

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The FDA and Barr said that they will take steps to try to enforce the age restriction. Plan B will be sold only in stores or clinics with a medical professional such as a doctor, nurse or pharmacist, not in gas stations or convenience stores, and isn't expected to be available through online pharmacies and other Web sites, Barr said.

The company agreed to send "anonymous shoppers" to test whether pharmacies are adhering to the rules. Barr will provide a booklet to be distributed with the drug that will explain how it works and its proper use.

'Adequate Safeguards'

Steven Galson, director of the FDA's drug center, said he believed the agency didn't have enough data about younger teens to approve the use of Plan B for them, and that they "would strongly benefit from consultation with health-care providers" before getting Plan B. The FDA can't absolutely ensure that people younger than 18 won't get the drug, he said, but the agency had "adequate safeguards in place ... to convince us this drug will be provided as per the labeling." He said other FDA officials within the FDA's drug center, who had endorsed over-the-counter Plan B without an age limit, disagreed with the final decision.

Barr said it expects use of the drug to grow. Currently, it is prescribed about 1.5 million times a year in the U.S. The company declined to project how much revenue would increase over the approximately \$30 million a year currently generated by Plan B's sales in the U.S. Barr's version of the drug is only sold in the U.S. and Canada. Other companies sell similar products elsewhere. Will Sawyer, specialty pharmaceuticals analyst at Leerink Swann & Co., predicted that Plan B sales may triple, to \$90 million, over the next three to five years. The company said it expected to price the two-pill Plan B regimen at least as high as the current \$25 to \$40 per prescription.

Bruce Downey, chief executive of Barr, said the company was "very happy" with the FDA's decision but planned to try to "lower or eliminate the age restriction" in the future. Major drugstore chains including **Walgreen Co.** and **CVS Corp.** said they would offer Plan B under the new FDA rules. A spokesman for **Wal-Mart Stores Inc.**, which declined to stock Plan B until March of this year, said the company is "still looking at details of what was approved and how the product can be sold and once we have those details we'll consider carrying the product for nonprescription sale." Wal-Mart Watch, a union-backed group that is critical of the giant retailer, said it would prod the company to offer Plan B under the new prescription-free conditions.

Barr said the newly labeled drug will be available "before the end of the calendar year."

Reproductive-rights groups said the need to present proof of age, and the age cutoff itself, might keep the drug from women and teens who need it. Cecile Richards, president of the Planned Parenthood Federation of America, said "putting in restrictions ... makes it less likely that it's going to be used and going to be effective." In the U.S., 34% of teenage girls get pregnant at least once before turning 20, a figure cited on the group's Web site. The Center for Reproductive Rights, which criticized the age restriction, said it planned to continue a lawsuit against the FDA over Plan B.

Potential Election Issue

The move could become an election-campaign issue. The decision is "very detrimental to some deeply held concerns" of her members, said Wendy Wright, president of Concerned Women for America. "I think they will have it in mind" as they vote. Her group called for the White House to

withdraw Dr. von Eschenbach's nomination. Yesterday, Republican Sen. Tom Coburn of Oklahoma said he opposed the FDA's decision.

Antiabortion groups have pressed for states to pass laws that would protect pharmacists' ability to refuse to provide certain drugs, including Plan B. The FDA's decision "does place pharmacists much more on the front line," said Daniel McConchie, executive director of Americans United for Life, which has lobbied for such legislation. His group would like to see states pass restrictions that could limit prescription-free availability of Plan B and is exploring the legal possibility of such state laws, he said. Barr's Mr. Downey said the company would fight any efforts to add sales restrictions, and Barr believes most pharmacists will be willing to dispense the drug.

For the FDA itself, the decision resolves a long-running and politically contentious issue. The original Plan B application had requested over-the-counter status, regardless of age. An FDA advisory committee voted in December 2003 to support that request. Memos that later leaked out showed that the head of the agency's own office of new drugs, as well as other reviewers, agreed. But in May 2004, the FDA's Dr. Galson rejected the change, citing the lack of data about the youngest teens.

Circuitous Route

Some steps in Barr Pharmaceuticals' effort to get Food and Drug Administration approval for over-the-counter sale of Plan B emergency contraception:

- **April 2003:** Women's Capital Corp. files an application to make Plan B available without a prescription.
- **December 2003:** FDA advisory committee votes in favor of over-the-counter sales.
- **May 2004:** FDA says it will not allow the pill to be sold without a prescription, citing concerns about young teens.
- **July:** Barr Pharmaceuticals files proposal to restrict sales to those age 16 and over.
- **August 2005:** FDA postpones decision, saying it must seek comment.
- **July 2006:** FDA says it can move ahead without creating a new regulation to allow the drug to be offered without a prescription to adults.
- **August:** Over-the-counter sales of Plan B for adults age 18 and over approved.

Barr, which had by then purchased rights to the drug from its original sponsor, then reapplied to the FDA, requesting that females 16 years and older be allowed to buy Plan B without a prescription.

Last August, the FDA's then-commissioner, Lester Crawford, postponed a decision, saying that the agency might need new regulations to enforce an age restriction, though the agency's career staff was willing to approve an over-the-counter version for those 17 and older. The agency's assistant commissioner for women's health, Susan Wood, resigned after that announcement, complaining that the FDA's handling of the drug hadn't been based on science. Dr. Crawford later resigned, though not over the Plan B issue.

But on July 31, the day before Dr. von Eschenbach was supposed to have a Senate confirmation hearing on his nomination, the FDA released a letter saying it didn't need to craft a new regulation. In a memo released yesterday, Dr. von Eschenbach said he concluded that 18 was the best cutoff age because it is a familiar one for states and pharmacies. Dr. Galson said in his own memo that he now concurred.

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